(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 047 806 A1

FI

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 80303258.0

(22) Date of filing: 16.09.80

(51) Int. Cl.³: A 61 B 5/14

(43) Date of publication of application:
24.03.82 Bulletin 82/12

(84) Designated Contracting States:
BE IT

(71) Applicant: AMERICAN HOSPITAL SUPPLY CORPORATION
One American Plaza
Evanston, IL 60201(US)

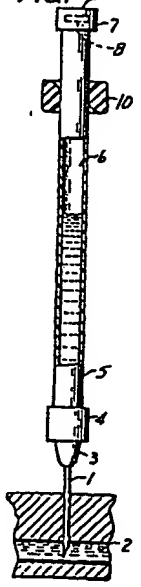
(72) Inventor: Akhavi, David S.
10966 Roebling, Apt. 6
Los Angeles California 90024(US)

(74) Representative: Johnson, Terence Leslie et al,
Edward Evans & Co. Chancery House 53-64 Chancery Lane
London, WC2A 1SD(GB)

(54) Blood sampler.

(57) A device particularly suited for collecting and dispensing an arterial blood sampler includes a needle (1) connected to a flexible transparent tube (5) that includes an air exit vent (7) with a nonwet filter (8) so air, but not blood, can exit the filter under arterial blood pressure. A clamp (10) on the tube (5) pinches off a segment of blood and longitudinally strips such blood segment from the tube (5). The tube (5) has an oxygen blocking coating (39) which is covered with a dry anticoagulant coating (40).

Fig.1



EP 0 047 806 A1

Blood Sampler

Technical Field of the Invention

This invention relates to a blood sampling device particularly suited for collecting a blood sample from a patient so that this blood sample can be tested for various gases which are dissolved in the blood.

Venous blood has long been collected for various medical tests. Recently it has become more important to also collect arterial blood for measuring of the partial pressures of dissolved oxygen and carbon dioxide in the arterial system. When collecting a blood sample, it is important to distinguish at the time of collection whether it is arterial or venous blood being collected.

Background Art

In the past, arterial blood has been detected by use of glass syringes in which the arterial blood pressure would be sufficient to force back the syringe plunger; venous pressure would not. U.S. Patent 3,930,429 also proposes a plastic syringe system for distinguishing arterial pressure. However, with plunger type arterial blood collectors, these plungers can sometimes catch and drag, making it difficult to clearly distinguish that the blood is arterial.

Recently others have proposed the use of a glass tube connected to a needle, thereby eliminating the plunger. Such devices require the use of a manually applied cork to plug the rear end of the glass tube to prevent the blood sample from spilling out. Because the glass tube was rigid, it was also difficult to dispense the blood sample into a machine that did not have a vacuum extractor for the blood sample. Because it did not have a plunger, such sample could not be forced into the machine.

Additional problems with prior arterial blood samplers have included transmission of oxygen through the sampler's wall to cause erroneous readings for the blood sample. Also, liquid heparin in the

sampler has introduced an error into the readings for oxygen and carbon dioxide. These problems are described in the following publications:

Scott et al, "Leakage of Oxygen From Blood and Water Samples Stored in Plastic and Glass Syringes," British Medical Journal, 28 August 1971, 3, pp. 512-516.

Hansen et al, "A Systematic Error in the Determination of Blood Pco_2," American Review of Respiratory Disease, Vol. 15, 1977, pp. 1061-1063.

Hamilton et al, "Arterial Blood Gas Analysis: Potential Errors Due to Addition of Heparin," Anaesthesia and Intensive Care, Vol. VI, No. 3, August 1978, pp. 251-255.

Disclosure of Invention

The present invention overcomes the problems described above and includes a blood sampler with a needle connected to a flexible reservoir tube having a vent closed by a valve (filter) structure which permits the explusion of gas from the reservoir, but not blood. A baffle structure on the needle prevents turbulent mixing of the blood and its overriding air as the blood fills the reservoir. A clamp on the flexible tuge segments the collected sample into an air contamination sample and a test sample, and this clamp can pinch the tube to strip the collected blood sample from the reservoir into a testing machine that does not have a vacuum sample extractor. The flexible tube has a gas blocking coating to prevent transmission of oxygen or carbon dioxide through the tube's wall. The tube also has an internal coating of dry anticoagulant (heparin).

Brief Description of Drawings

Figure 1 is a front elevational view of the blood sampler partially filled with the blood sample; Figure 2 is a view similar to Figure 1 with the sampler filled with the blood sample; Figure 3 is an enlarged sectional view of the needle adapter and showing an alternative form of the vent structure; Figure 4 is a view of the packaged sampler; Figure 5 is an enlarged view taken along line 5-5 of Figure 3; Figure 6 is an enlarged

view of the first baffle structure taken along line 6-6 of Figure 3; Figure 7 is a view of the sampler connected with the testing machine; and Figure 8 is a fragmentary view showing a second baffle structure in the form of a ball.

Best Mode for Carrying Out the Invention

In Figure 1, a needle including a cannula 1 is shown inserted into a patient to tap arterial blood 2. The needle includes a hub 3 which is attached by means of a needle adapter 4 to a transparent flexible plastic tube 5 forming a blood collection reservoir. This plastic tube 5 can be of a thermoplastic or thermoset material which has elastomeric or rubber like properties so it can be pinched shut and reopened upon removal of the pinching forces. In Figure 1, blood is shown welling up in the reservoir tube by means of arterial blood pressure and forcing the overriding air 6 out through a vent 7. Vent 7 includes a one-way valve structure 8 in the form of a "nonwet" filter. Such filter will permit the passage of gas, such as sterile air, from the reservoir, but will not permit the passage of blood.

The details of a first embodiment of the vent and nonwet filter structure of Figure 1 is shown in detail in Figure 2. In Figure 2, the complete blood sample has been collected and a clamp 10 has been positioned along the reservoir 5 and the flexible tube is pinched shut by clamp 10 to segregate the collected blood sample into an air contaminated segment 11 and a test segment 12. Thus, any change in the oxygen or carbon dioxide partial pressure of the blood caused by its contact with air is minimized by segmenting sample 11 from the test machine. With a blood sampler, it is customary to stick the needle into a rubber plug (not shown) to prevent leakage. If desired, the rubber plug could be inside a needle protector 13. An alternative way of containing the sample is to remove the needle and place a syringe cap (not shown) on a tip of the syringe.

As previously mentioned, it is important to minimize the turbulent contact with the blood sample and air, particularly when the sample taken is arterial blood in which the partial pressure of oxygen and carbon dioxide are to be measured. In Figure 3, the needle adapter has a special structure for minimizing air bubble hangups when collecting the sample. The needle adapter 4 has a tubular structure with an internally beveled

lower end 15 and an internally beveled upper end 16. Tests have shown that such structure causes the blood sample to smoothly well up in the collecting reservoir. For instance, when end 15 was at 90 to the longitudinal axis of the adapter, air bubbles continuously formed at such intersection of the needle adapter and hub 3.

The needle hub 3 is firmly held to the needle adapter by an internally threaded collar 17. The needle hub also includes a structure which prevents the turbulent mixing of the blood sample and air, particularly during an inrush of arterial blood. The needle hub of Figure 3 is shown with a first baffle structure 19 that can be snap fitted into an undercut groove 20 in the hub, or press fitted into a hub without undercut, or otherwise secured to the hub. Preferably, the baffle structure as shown in Figure 6 has one or more openings, such as 22 and 23, which combine to form a passage at least as large as an internal diameter of cannula 1. By such large passage to the baffle structure, the inflow of blood from an arterial source is not sufficiently slowed down so as to be confused with venous blood under a much lower pressure. The baffle system is not intended to be a high pressure drop filtering system which might so restrict the flow of blood that it would take an inordinate amount of time to collect the sample.

The baffle of Figure 6 includes a peripheral ring 24 which is bridged by a central bar 25. If desired for molding purposes, an enlarged central section 26 can be added for a mold gate. An alternative form of a baffle, shown in Figure 8, is a ball in the needle that can prevent turbulent blood and air mixing and yet does not interfere with the flow rate distinction between arterial and venous blood.

In the second embodiment of the vent structure shown at 30 of Figure 3, an internally tapered extension 31 is provided. Extension 31 can receive a hypodermic syringe if it is desired not to use the clamp 10, but to force the blood sample out of the reservoir into the testing machine. Such extension 31 could also be used with a syringe to apply a vacuum to the reservoir for collecting slow flowing venous or arterial blood.

Once the blood sample has been collected, the protector and needle can be removed and the needle adapter joined directly to a testing machine 36 to measure the partial pressure of oxygen and carbon dioxide in the arterial blood sample. Most such testing machines include a very

small tubular probe that fits inside the reservoir and sucks out a measured amount of blood for the test.

In some machines that do not have such an automatic vacuum extractor, a clamp can be used to manually strip the blood sample into the machine. This can be done either by sliding a clamp, such as schematically shown at 10, along the tube. Alternatively, a roller type clamp, such as schematically shown at 37, could be used to roll along the flexible tube reservoir. When a clamp such as 10 is used for sliding, it is preferable to coat the outer surface of the tube or internal surface of the clamp with a lubricant, such as silicone or a teflon coating shown at 38 in Figure 5.

It has been found that a reservoir 5 of polyurethane remains flexible and highly squeezable even when subjected to ice bath storage at 0° C. This flexibility is useful in expelling the sample and also rolling the tube in the hands to remix any separated plasma and hemoglobin prior to testing. Such rolling feature also helps to mix the blood with an anticoagulant. Another material that remains flexible and squeezable is a blank copolymer, marketed under the trademark KRATON, by Shell Chemical Company. However, KRATON does not work as well as polyurethane because of its more limited transparency and more tacky external surface making it more difficult to slide a clamp, such as clamp 10. Preferably, the tubular reservoir has a Shore A hardness of 40 to 100.

As mentioned in the publications above, it is highly critical to minimize any transmission of oxygen or carbon dioxide across the reservoir wall 5. Because polyurethane is somewhat pervious to oxygen and carbon dioxide, an internal gas blocking barrier coating or layer 39 is applied to the inner surface of the polyurethane reservoir. This blocking coating which prevents transmission of oxygen and carbon dioxide can be a copolymer of vinylidene chloride and acrylonitrile, which is also known under the trademark SARAN.

This gas blocking coating is further covered with a dry anticoagulant 40, such as heparin. Because the heparin is in dry form, it has very little geometric volume to substantially change the partial pressure of oxygen or carbon dioxide in the blood to cause errors.

Figure 4 shows the blood sampler in a package 41 which preferably maintains the sampler in sterile condition until ready to use. The

package can then be opened and the sampler is extremely useful for collecting and dispensing an arterial blood sample. However, it can also be useful in collecting a venous blood sample, but the inflow of blood would be much slower unless a vacuum were applied by syringe to the Figure 3 embodiment.

The blood collecting reservoir can have an internal diameter of 2.54 mm to 7.62 mm (.100 to .300 inch), a wall thickness of .25 mm to 2.54 mm (.010 to .100 inch), and a length of 5.1 cm to 30.5 cm (2 to 12 inches) for an adult blood sample. A smaller diameter tube could be used for collecting a blood sample from an infant.

In the above description, specific examples have been used to describe the invention. However, it is understood by those skilled in the art that certain modifications can be made to these examples without departing from the spirit and scope of the invention.

CLAIMS

1. A blood sampler having a needle connected to a blood reservoir, characterised by a gas (6) in the reservoir (5), by the reservoir (5) having a vent (7) with a filter (8) through which the gas (8) can be expelled by pressure of blood entering the reservoir (5), and by the filter (8) preventing the escape of blood from the reservoir (5).

2. A blood sampler according to Claim 1, characterised in that the gas (6) is sterile air.

3. A blood sampler according to Claim 1 or 2 characterised in that the gas (6) can be expelled through the filter (8) by means of arterial blood pressure.

4. A blood sampler according to any preceding Claim, characterised in that the reservoir (5) is an elongated flexible transparent tube that is resiliently compressible by lateral pinching at temperatures as low as $0^{o}C$, and in that the tube can be pinched shut at a location to segregate a portion of the collected blood sample and this blood sampler portion can thereafter be squeezed out of the flexible tube reservoir (5) for testing.

5. A blood sampler according to any preceding Claim, characterised in that the reservoir (5) has a coating (39) that prevents gases from a collected blood sample from passing through a wall of the reservoir (5).

6. A blood sampler according to Claim 5, characterised in that the reservoir (5) is of a polyurethane material and has a coating (39) of a copolymer of vinylidene chloride and acrylonitrile.

7. A blood sampler according to any preceding Claim, characterised in that the reservoir (5) contains an anticoagulant.

8. A blood sampler according to Claim 7 characterised in that the (5) anticoagulant is a dry coating (40) on an inner surface of the reservoir (5).

9. A blood sampler according to Claim 8, characterised in that the dry anticoagulant coating (40) on an inner surface of the reservoir (5) is heparin.

10. A blood sampler according to any preceding Claim characterised in that the blood sampler has a baffle (19) to disperse blood rushing into the reservoir (5).

FIG.1

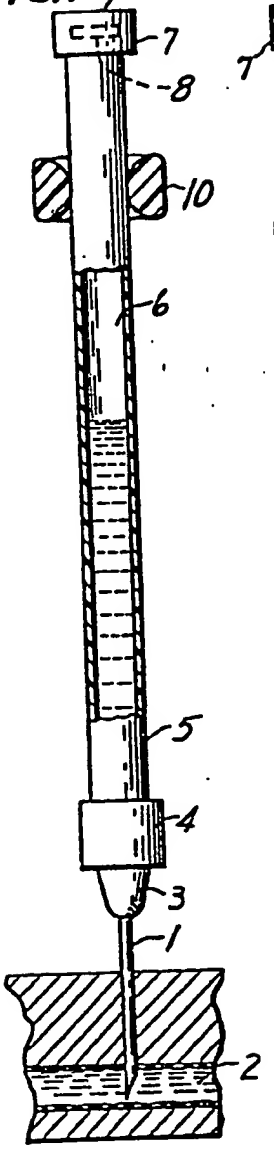


FIG.2

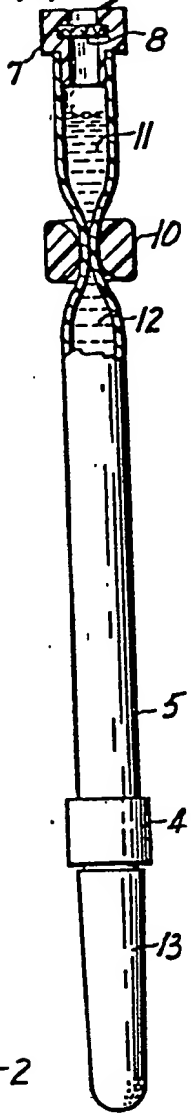


FIG.3

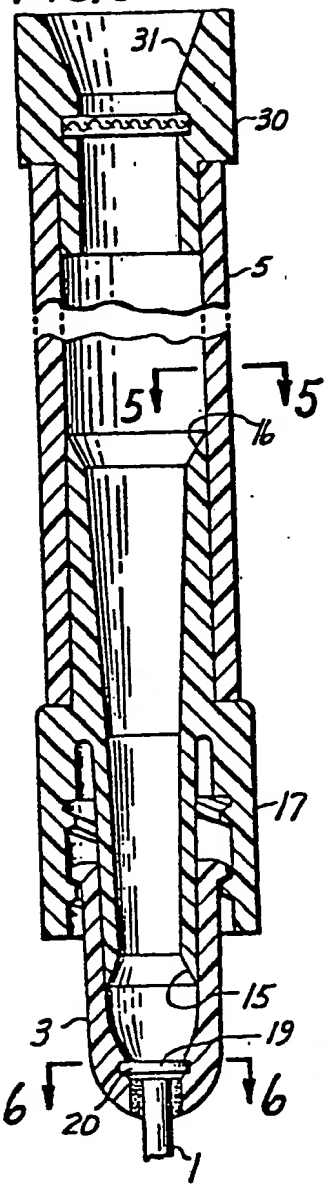


FIG.4

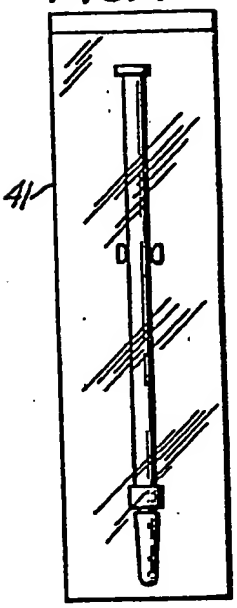
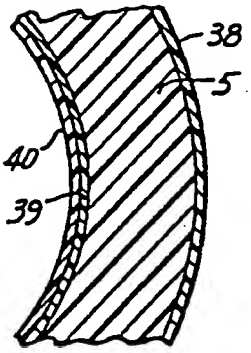


FIG.5



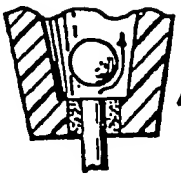
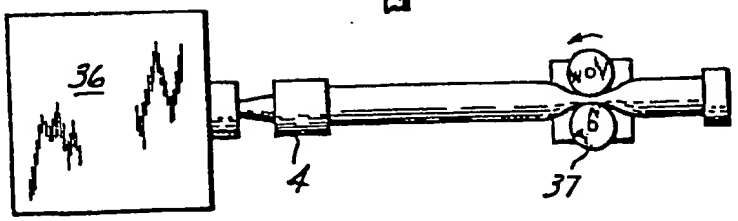


FIG.8

FIG.7



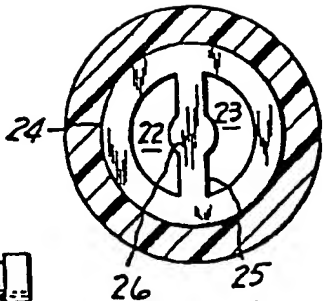


FIG.6

European Patent Office

EUROPEAN SEARCH REPORT

Application number
0047806
EP 80 30 3258

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
X	US - A - 3 960 139 (D.L. BAILEY) * Abstract; column 1, lines 62-68; column 3, line 9 to column 4, line 13; figures 1-3 *	1,3, 7-9
X	US - A - 3 978 846 (D.L. BAILEY) * Abstract; column 1, line 44 to column 2, line 29; column 3, line 54 to column 4, line 43; figures 1-3 *	1,3, 7-9
	US - A - 4 133 304 (D.L. BAILEY) * Abstract; column 1, line 55 to column 2, line 24; column 3, line 4 to column 5, line 35; figures 1-4 *	1,3, 7-9
	US - A - 3 867 923 (R.J. WEST) * Abstract; column 3, lines 28-47; column 7, lines 57-61* figures 1 and 2 *	1,4,7
	US - A - 3 785 367 (R.F. FORTIN et al.) * Abstract; column 2, lines 10-35; figures 1-3 *	1,4
	US - A - 4 187 861 (B.T. HEFFERNAN) * Abstract; column 3, lines 28-33, 48-50; figures 1-4 *	1,4, 7,8
	US - A - 3 698 561 (A.L. BABSON) ./.	1,4,6

CLASSIFICATION OF THE APPLICATION (Int. Cl.³)
A 61 B 5/14

TECHNICAL FIELDS SEARCHED (Int. Cl.³)
A 61 B 5/14
A 61 M 5/28
A 61 M 5/34

CATEGORY OF CITED DOCUMENTS
X: particularly relevant
A: technological background
O: non-written disclosure
P: intermediate document
T: theory or principle underlying the invention
E: conflicting application
D: document cited in the application
L: citation for other reasons
&: member of the same patent family, corresponding document

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	19.05.1981	BEAVEN

EPO Form 1503.1 06.78

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl.³)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
	* Abstract; column 2, lines 28-36; figures 1-3 *		
	US - A - 2 615 446 (P.B. LINGENFELTER)	4,6	
	* Column 1, lines 8-31; column 2, lines 12-21; figures 1-4 *		
			TECHNICAL FIELDS SEARCHED (Int. Cl.³)